PAIN RELIEVER PM EXTRA STRENGTH- acetaminophen and diphenhydramine hydrochloride tablet
Mckesson (Sunmark)

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

Active ingredients (in each caplet)

Acetaminophen 500 mg

Diphenhydramine HCl 25 mg

Purpose

Pain reliever

Nighttime sleep aid

Uses

temporary relief of occasional headaches and minor aches and pains accompanying sleeplessness

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
- more than 2 caplets in 24 hours, which is maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Do not use
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with other products containing diphenhydramine, even one used on skin
- in children under 12 years of age
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have
- liver disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed (see overdose warning)**

adults and children 12 years and over	• take 2 caplets at bedtime • do not take more than 2 caplets of this product in 24 hours
children under 12 years	do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store at room temperature 15º- 30º C (59º- 86º F), avoid high humidity and excessive heat

Inactive ingredients

colloidal silicon dioxide*, croscarmellose sodium*, D&C Yellow #10 Aluminum Lake*, FD&C Blue #1 Aluminum Lake, FD&C Blue #2 Aluminum Lake, hypromellose, magnesium silicate*, magnesium stearate*, microcrystalline cellulose, mineral oil*, polyethylene glycol, polyvinyl alcohol*, povidone, pregelatinized starch, silica*, sodium starch glycolate*, stearic acid, talc*, titanium dioxide, triacetin*, and yellow iron oxide*

*contains one or more of these ingredients

Questions or comments?

Call toll free **1-877-753-3935 Monday- Friday 9AM- 5PM EST**

Principal Display Panel

Compare to TYLENOL® PM active ingredients**

Pain Reliever PM

extra strength

sleep aid for pain with sleeplessness

ACETAMINOPHEN 500 mg

DIPHENHYDRAMINE HCl 25 mg

**This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® PM

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Product Label

Pain reliever PM

PAIN RELIEVER PM EXTRA STRENGTH
acetaminophen, diphenhydramine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:49348-918
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE	
CROSCARMELLOSE SODIUM	
D&C YELLOW NO. 10	
FD&C BLUE NO. 1	
FD&C BLUE NO. 2	
HYPROMELLOSES	
MAGNESIUM SILICATE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
MINERAL OIL	
POLYETHYLENE GLYCOLS	
POLYVINYL ALCOHOL	
POVIDONES	
STARCH, CORN	
SILICON DIOXIDE	
SODIUM STARCH GLYCOLATE TYPE A CORN	
STEARIC ACID	
TITANIUM DIOXIDE	
TRIACETIN	
FERRIC OXIDE YELLOW	
TALC	

Product Characteristics

Color	BLUE (Light blue)	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	S525;V15;AV;CPC752
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-918-10	1 in 1 CARTON		
1		100 in 1 BOTTLE		

2	NDC:49348-918-09	1 in 1 CARTON		
2		50 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	05/24/2011	

Labeler - Mckesson (Sunmark) (177667227)

Revised: 9/2012 Mckesson (Sunmark)